

REMARKS

This Amendment accompanies Applicants' concurrently filed Request for Continued Examination.

Status of the Claims

Claims 24-59 were pending and were rejected in the final Office Action mailed 8 June 2005. By this Amendment, claims 24-59 are canceled without prejudice or disclaimer and replaced with new claims 60-83, of which examination is requested.

Structure Drawing Amendment

The structure drawing on page 11 has been amended to correct a minor error in the substitution pattern on the phenyl ring in the lower right-hand portion of the molecule.

Response to Disclosure Objection

The disclosure is objected-to as lacking complete US application numbers at pages 12 and 18. Applicants have made appropriate amendments and thus respectfully request withdrawal of the objection.

Response to Written Description Rejection

Claims 32, 34-36, and 38-59 are rejected under 35 USC § 112, ¶ 1, as allegedly lacking written description. Certain claim language is cited in the rejection as causing the rejection, however no explanation or basis for the rejection is set forth.

Applicants respectfully disagree with the rejection, although the rejection is believed to be moot in view of the cancelation of the rejected claims.

Nonetheless, Applicants wish to point out some of the portions of the specification lending support for rejected subject matter. For example, p. 17, ¶ 66 discloses regimens having 1000 mg and 500 mg first doses and 500 mg and 250 mg second doses of dalbavancin. At p. 19, ¶ 75, there is disclosed treatment of complicated and uncomplicated skin infections. Susceptible bacteria are disclosed as including, *e.g.*, those at p. 6, ¶ 20.

Response to Double-Patenting Rejections

Claims 25-59 are rejected for alleged obviousness-type double patenting over claims 1-22 of US Patent No. 6,900,175.

Without prejudice, Applicants are filing concurrently herewith a terminal disclaimer over the cited patent in order to expedite prosecution of the present application. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 24-59 are provisionally rejected for alleged obviousness-type double patenting over claims 12-24, 28-32, 37-43, and 54-66 of Appln. No. 10/828,439.

Claims 24-59 are provisionally rejected for alleged obviousness-type double patenting over claims 1-45 of Appln. No. 10/828,483.

With respect to these two latter rejections, Applicants submit that it is not known when or whether the cited claims will issue. Accordingly, Applicants will address the rejections directly once the claims are allowed, as the claims may change or be canceled during prosecution.

Response to Obviousness Rejection

Claims 24-59 are rejected as allegedly being unpatentable under 35 USC § 103(a) over "Dalbavancin Tested for Soft Tissue Infections" (2001) or "Molecule of the Month V-Glycopeptide" (2000) for the reasons given in the 12 January 2005 Office Action. The present rejection states that the data presented in the specification is limited to wherein the first dose is two times the second dose, that the claims are not so limited, and that there is no evidence of improved efficacy when the second dose is four times less, the same, or larger than the first dose.

Applicants respectfully disagree with the rejection, but have canceled the rejected claims without prejudice or disclaimer, and submit that the rejection is now moot.

The new claims recite a method of treating Gram-positive bacterial infection comprising, *inter alia*, giving a first dose containing about 500 to 5000 mg dalbavancin followed by a second dose about five to ten days later, wherein the first dose contains about 1.5 to 3 times the amount of dalbavancin in the second dose.

Thus, the claims provide a ratio range definitely bounded at each end at about 1.5 and 3 times the second dose, respectively. Of course, because the first dose is larger, the lower the ratio, the larger the second dose will be. For example, according to claim 60, a 1000 mg first dose might correspond to a 500 mg second dose (2x) or a 667 mg second dose (1.5x). It is respectfully submitted, therefore, that lowering the ratio from 2 to 1.5 *increases* the second dose and would therefore be expected to match or improve on the efficacy of a 2x regimen. With respect to a 3x ratio, efficacy would also be expected to be at least comparable to a 2x regimen. For example, a 1000 mg first dose would call for a 333 mg second dose. Based on the data, such a regimen would also be expected to improve upon the results of a single dose regimen. Accordingly, Applicants respectfully submit that the previous rejection is not fairly applicable to the new claims.


Conclusion

In view of the above, Applicants respectfully submit that the pending claims are allowable in their present form, and that the application is otherwise in condition for allowance. The Examiner is respectfully requested to withdraw the rejection and, as the next official action, to provide a Notice of Allowance.

If any issues remain which can be resolved by a telephone conference, or should the Examiner have any questions or comments regarding this matter, the Examiner is respectfully invited to contact the undersigned at the telephone number shown below.

Date: 4 Nov 05

Respectfully submitted,


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